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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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**GROUP 1600** 

Application Number: 09/638,102
Filing Date: August 11, 2000

Appellant(s): SCHWARTZ, DAVID C.

David C. Schwartz
For Appellant

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed March 9, 2006 appealing from the Office action mailed February 6, 2006.

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#### (1) Real Party in Int r st

A statement identifying by name the real party in interest is contained in the brief.

#### (2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

#### (3) Status of Claims

The statement of the status of claims contained in the brief is correct.

#### (4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

#### (5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

### (6) Grounds of Rejection to be reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

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#### (7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### (8) Evidence Relied Upon

4,867,946	GROSS ET AL	9-1989
4,281,061	ZUK ET AL	7-1981
6,156,494	ADAMS ET AL	12-2000
6,372,895	BENSTEN ET AL	4-2002

#### (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 41, 43, 45-46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (USP# 4,867,946) in view of Zuk et al (USP#4,281,061).

The instant claimed invention is drawn to a *chemical screening kit* which examiner still maintains applicant has not shown support for this limitation. The teaching of Gross et al was cited against the kit claims in the Office Action mailed October 19, 2004 and are set forth below for convenience.

Gross et al teaches the instant claims by teaching a device for evaluating test strips used to screen a variety of different samples. The test strips contain several test sections where the reagents are placed for testing (col. 1, 2<sup>nd</sup> para and see Figure 2). The device has a platform and a holder to support the test strips (col. 2, see claim 1) in

a parallel relationship in which the test strips are perpendicular to the holder (see Figure 2). The test strip has test sections spaced along the strips to allow samples to be deposited (see Figure 2).

Although the reference of Gross et al teaches the components of the instant claimed invention, they are silent with respect to a kit.

However, Zuk et al. teaches that "as a matter of convenience the reagents can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been <u>prima facie</u> obvious to one of ordinary skill in the art at the time of applicant's invention to take the reagents and other materials as taught by Gross et al and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit along with other materials. One in the art would be motivated to because the reagents in a kit are available in pre-measured amounts which eliminates the variability that can occur when performing the assay

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Zuk and in further view of Adams (USP#6,156,494).

The teachings of Gross et al in view of Zuk et al are set forth above but is silent with respect to the strips being glass fibers.

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However, Adams et al teaches methods for utilizing optical fibers as a solid support for the assembly of combinatorial compounds. The optical fibers are used to direct light, heat or a combination thereof (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Gross et al to include glass fiber strips as taught by Adams et al to direct heat and light or a combination thereof to compounds on the surface of the fibers (see abstract) so compounds can be screened for binding activity.

Claims 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Zuk et al and in further view of Bensten et al ((USP#6,372,895).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not particularly point out strips that include a marker selected from the group of printing and fluorescent material.

However, Bentsen et al teaches in one of his embodiments an apparatus that uses a test strip that contains a printed barcode wherein the printed material on the barcode has an enzyme or spore. The strip is further sterilized and dipped into a buffer solution containing Fluorescence Enzyme Substrate (FES). If enzyme activity is present, the printed pattern will become detectable (col. 20, lines 66-67 and col. 21, 1<sup>st</sup> para).

It would have been obvious to one of ordinary skill in the art to have incorporate the printed barcode as taught by Bentsen et al into the strips of Gross et al to detect enzyme activity. Application/Control Number: 09/638,102 Page 6

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#### (10) Response to Argument

1. Applicant argues that the reference of Gross neither teaches nor suggests the concept of providing a library of test strips having different linear arrays of chemical compounds which can be combined together to provide a semi-custom planar array. Applicant further argues that the test strips of Gross are identical and the array provided on the holder of the device for analysis will always be the same and cannot be customized in any way. These arguments have been fully considered but not found to be persuasive.

In response, the concept and the suggestion of the instant invention is taught by Gross and deemed to be obvious. Gross teaches a library of test strips having different linear arrays of chemical compounds along each test strip. In column 1, lines 1-5, Gross discloses the different test to be determined from a urine sample. These samples are bilirubin, urobilinogen, ketone bodies, ascorbic acid, glucose, protein, nitrite, pH and the presence of blood in urine. There are individual sections along each test strip that provides for a different test reagent that corresponds to each different compound to be determined. Although applicant contends that all the test reagents along the test strip are the same, it would not make sense to one of ordinary skill in the art to make the reagents along the test strips the same when one is testing individual strips. Therefore, the examiner interprets each test section along each test strip to be different. This suggest to the skilled artisan that each strip can be designed to test for any of the above mentioned compounds (bilirubin, urobilinogen, k tone bodies,

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ascorbic acid, glucose, prot in, nitrite, pH and blood) that can be found in urine.

Therefore, the strips can be customized or designed for whatever clinical test that needs to be performed (see Figure 2).

2. Applicant argues that Gross test strips are positioned on the frame after they are exposed to the material to be screened and does not teach providing the strips on a frame and exposing all of the strips simultaneously. This argument have been fully considered but not found to be persuasive.

In response, merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Ex parte Rubin, 128 U.S.P.Q. 440 (P.O.B.A. 1959). Cohn v. Comr. Patents, 251 F. Supp. 437, 148 U.S.P.Q. 486 (D.C. 1966). Further, the claims have open "comprising" language and therefore do not prohibit the teaching of exposing the test strips to the material to be screened before being attached to the holder.

3. Applicant argues that Zuk fails to disclose any type of test strip or frame and therefore the combination of Gross and Zuk does not provide all of the elements of claim 41. Applicant further argues that one of ordinary skill in the art would not be motivated to combine Gross and Zuk because the kit taught by Zuk would neither enhance the sensitivity of a method nor eliminate variability. Applicant contends that the test strips disclosed by Gross already include pre-measured amounts of reagents

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and therefore there is not need to eliminate variability. These arguments have been noted but not found to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gross teaches that the object of the invention is to provide a device in modular construction which is suitable for economically investigating small members of test strips in medical practices and mobile facilities (column 1, lines 24-28). For this reason, Zuk can be combined to create a kit concept because kits are convenient for small office practices and mobile units for medical testing on a small scale. Kits are prepackaged in pre-measured forms for convenient use that would eliminate variability that would in turn enhance sensitivity. In determining obviousness, a combination of references need not result precisely in applicant's structure. Rather, the question is whether the invention would have been obvious in light of the combination. In re Thornberg, 103 F. 2d 387 (C.C.P.A. 1939). One of ordinary skill in the art would modify Gross to include kits because they are convenient.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Deborah A. Davis Patent Examiner Art Unit 1641

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Conferees:

February 6, 2006 Long Le, SPE, AU 1641 Larry Helms, AU 1643

LAPRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER